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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,664	02/03/2006	Gisela G Chiang	13751-036US1/A167 US	7404
26168	7590	01/05/2009		
FISH & RICHARDSON P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER YU, MISOOK	
			ART UNIT 1642	PAPER NUMBER
			NOTIFICATION DATE 01/05/2009	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

### Office Action Summary

**Application No.**

10/519,664

**Applicant(s)**

CHIANG ET AL.

**Examiner**

MISOOK YU

**Art Unit**

1642

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1, 6-11, 14-16, 18, 20 and 25-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 6-11, 14-16, 18, 20 and 25-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/02)  
Paper No(s)/Mail Date 10/22/2007.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Allowable Subject Matter***

Applicant is advised that the Notice of Allowance mailed on 11/24/2008 is vacated. This Office action is based on the claims presented with the after-final amendment submitted on 09/16/2008.

Prosecution on the merits of this application is reopened on claims 1, 6-11, 14-16, 18, 20, 25-34 considered unpatentable for the reasons indicated below:

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9, 10, 11, 18, 20, and 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Mastrangelo et al (IDS AP filed on 10/22/2007) Biotechnology and bioengineering vol. 67, pages 544-554 .

Claims 1, 9, 10, 11, 18, 20, and 28-31 are drawn to Bcl-Xl over-expressing CHO cells comprising an expressing vector encoding a secreted protein, wherein the CHO cell does not express a heterologous cyclin-dependent kinase inhibitor, and a method of producing the secreted protein .

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Mastrangelo et al., teaches on pages 551-552 that Bcl-XI over-expressing CHO cells comprising IL-2 (a secreted protein) and a method of isolating the protein expressed in CHO cell transfected with Bcl-XI over-expressing vector.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 7, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mastrangelo et al (cited above) in view of Sinacore et al., *Biotechnology and bioengineering* , 1996, vol. 52, no4, pp. 518-528.

Claims 6, 7, 25 and 26 are drawn to the CHO cells of the respective base claims adapted for growth in suspension in a medium free of serum.

See above for what Mastrangelo et al., teaches. Mastrangelo et al., does not teach growth of the CHO cells in suspension in a medium free of serum.

However, Sinacore et al., teaches a strain of CHO cells “capable of robust growth in serum-free suspension culture” and also teaches that these CHO cells “provides an opportunity for reducing the time and resources required to develop large-scale, suspension culture-based manufacturing processes employing serum-free medium”. Note the abstract and title.

Therefore it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention with a reasonable expectation of success since

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Sinacore et al., teaches a CHO cell strain adapted to grow in suspension in a serum free medium. One of ordinary skill in the art would have been motivated to arrive at the claimed invention given the advantage of saving time and other resources of using the CHO cell strains as taught by Sinacore et al.

Claims 14-16 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mastrangelo et al (cited above) in view of Kim et al (IDS filed on 10/22/2007, Biotechno Bioeng 71, 184-193).

Claims 14-16 and 32-34 are drawn to Bcl-XL over-expressing CHO cells comprising an expressing vector encoding an antibody.

See above for what Mastrangelo et al., teaches. Mastrangelo et al., does not teach expressing an antibody in the CHO cells. However, Kim et al., teaches CHO cells have been used to produce an antibody.

Therefore it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention with a reasonable expectation of success since Kim et al., teaches how to express an antibody in CHO cells. One of ordinary skill in the art would have been motivated to use Bcl-XL over-expressing CHO cells to produce an antibody since Mastrangelo et al teaches that the overall production of a protein is much higher in those cells

Claims 8 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mastrangelo et al (cited above) as applied to claims 1, 718, 26

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in view of Sinacore et al (cited above) and in further in view of Kim et al (cited above)

Claims 8 and 27 are drawn to CHO cell adapted for growth in a serum free medium comprising butyrate.

Mastrangelo et al., teaches the CHO cells and Sinacore et al., teaches serum free medium. Neither Mastrangelo nor Sinacore et al., teaches butyrate.

However, Kim et al., teaches that butyrate has been used in recombinant CHO cell cultures for high level expression of foreign proteins (note page 184, right column) but has drawback of causing apoptosis.

Therefore it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention with a reasonable expectation of success since Kim et al., teaches how to use butyrate in the growth medium.

One of ordinary skill in the art would have been motivated to use butyrate since it increases a foreign protein production in the CHO cells as taught by Kim et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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